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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,557	08/18/2000	Brydon L. Bennett	10624-046-999	6892

20583 7590 09/21/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,557

Applicant(s)

BENNETT ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 24-35, 38 and 40-55 is/are pending in the application.
4a) Of the above claim(s) 28-33 and 40-46 is/are withdrawn from consideration.
5) ☒ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 6-8, 24-27, 34, 35, 38 and 47-55 is/are rejected.
7) ☒ Claim(s) 4 and 5 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-8, 24-35, 38 and 40-55 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2005 has been entered.

Election/Restrictions

During a telephone conversation with

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Mr. Michael Bruner on July 6, 2004, a provisional election was made with traverse to prosecute the invention of Group I (drawn to products). The requirement was deemed proper and made FINAL in a previous Office Action.

Claims 28-33 and 40-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

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The indicated allowability of claims 1, 2, 6-8, 25, 34, 35 and 38, 51 and 53 is withdrawn. Rejections based on the newly cited reference(s) follow.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3, 6-8, 25, 27, 34, 35, 38 and 47-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-18 and 21-23 of copending Application No. 10/395,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically described in the copending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products

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which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

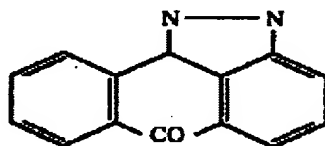
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 24 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Tzikas {U.S. Pat. 4,202,827}.

Tzikas disclose Example 12 in water (column 4).

volume of water. The suspension is then poured into a mixture of ice and water and filtered. The filter cake is washed neutral with water and dried, affording 22.2 parts of pyrazolanthrone of the formula.



(4).

Response to Arguments

Applicants' arguments filed June 9, 2005 have been fully considered. Applicants argue that Tzikas et al. do not describe anything which one skilled in the art would consider being a pharmaceutical composition. In response, and as stated in the previous Office Action, instant claim 24 is directed to a pharmaceutical composition comprising a compound and a pharmaceutically acceptable carrier. Tzikas disclose

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Example 12 in water (column 4, lines 42-54). It is known in the pharmaceutical art that water is useful as a liquid carrier in pharmaceutical compositions. See, for example, column 39, lines 62-64 in Showalter et al. {U.S. Pat. 4,556,654}. Therefore, all of the claims limitations have been met.

Applicants argue that the slurry of anthrapyrazole in water resulting from the process of Example 12 may or may not still contain sulfuric acid and therefore not an acceptable formulation for human administration and not a pharmaceutical composition. Applicants argue that on page 23, lines 2-3 of the instant specification, Applicants teach that sterile water as a possible pharmaceutically acceptable carrier.

Applicants also argue that Tzikas et al. teach that the anthrapyrazole compounds are useful as vat dyes and therefore, the synthesis and isolation of which would not require pharmaceutical grade solvents.

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In response, Tzikas et al. teach that the filter cake is washed neutral with water. Therefore, one skilled in the art would assume that, if not all, most of the sulfuric acid has been washed away or that trace amounts may be present. The rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 3, 26, 27, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showalter et al. {U.S. Pat. 4,556,654}.

*Determination of the scope and content of the prior art (MPEP
§2141.01)*

Applicants claim pyrazoloanthrone compounds. Showalter et al. (column 1; column 21, lines 38-62; column 35, lines 64-68; columns 39-42; and especially the 1st, 6th and 8th compounds in columns 25-26) teach pyrazoloathrone compounds that are structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

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***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-tumor agent).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful, for example, in treating tumors. Absent a side-by-side showing of unexpected, beneficial and superior results, the instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed June 9, 2005 have been fully considered. Applicants argue that: (1) although the claimed subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness and cite In re Baird, 16 F.3d 380, 382 (Fed. Cir. 1994); (2) there must be some suggestion or motivation, either in the cited reference or generally known to one of ordinary skill in the art, to modify the reference to arrive at the claimed compounds; (3) the Examiner must point to some source of motivation for one of ordinary skill in the art to pick and choose the particular variable from the generic class of Showalter to arrive at the claimed invention; and (4) Showalter et al. do not provide the requisite motivation to arrive at the claimed subgeneric classes and teaches away from the claimed invention when considered as a whole.

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All of Applicants' arguments have been considered but have not been found persuasive. It is disagreed that Showalter et al. do not direct one skilled in the art toward the instant claimed invention. Unlike in In re Baird, Showalter et al. teach Applicants' anthra[1,9-cd]pyrazole-6(2H)-one core. Further, Showalter et al. teach a first generic compound (column 1, lines 18-64), a second generic chemical compound (column 2, lines 10-58) and a third generic chemical compound (column 3, lines 3-56), all teach Applicants' claimed invention. Additionally, Showalter et al. prepare numerous specie having the anthra[1,9-cd]pyrazole-6(2H)-one core. It would appear that Applicants' are arguing that if no rejection under 35 USC § 102 cannot be made, a rejection under 35 USC 103 should not be made. However, this rationale is not the basis of a rejection under 35 USC § 103.

Applicants argue that: (1) although a reference is not limited to the preferred or working embodiments,

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portions that lead away from the claimed invention must also be considered; (2) the structure-activity relationship data as a whole set forth in Showalter et al. would discourage one of ordinary skill in the art from selecting a subgenus wherein Z is H, or at the very least, does not provide the requisite motivation to select such a subgenus; (3) the table in columns 25-28 does not provide any motivation to one of ordinary skill in the art to select a subgenus of compounds wherein N-2 is unsubstituted, although Applicants' acknowledges that compound 6 in the table, which is unsubstituted, has better activity than some compounds which are N-2 substituted; (4) the *in vitro* data against human colon adenocarcinoma cells in columns 37-38 of Showalter et al. does teach away from the presently claimed compounds; and (5) a comparison of listed compounds 4, 5 and 18 show that the N-2 unsubstituted compound has less activity than a N-2 substituted compound.

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In response, again, it is disagreed that the structure-activity relationship data as a whole set forth in Showalter et al. would discourage one of ordinary skill in the art from selecting a subgenus wherein Z is H. Further, the compounds found in the table in columns 25-28 do direct one skilled in the art toward the instant claimed compounds. As shown in compound 6 in the table in columns 25-28 and the fourth compound listed in columns 37-38, these N-2 unsubstituted compounds have activity and the activity is better than some of the N-2 substituted compounds. In looking at listed compound 29 in columns 37-38, one skilled in the art might also speculate that the difference in activity is due to the -NRY group. Applicants' have focused on comparing the activity shown of the various compounds in the prior art reference instead of providing a persuasive showing of unexpected, beneficial and superior activity of the instant claimed compounds over the prior art. Absent a

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side-by-side persuasive showing of unexpected, beneficial and superior results, the instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Allowable Subject Matter

Claims 4 and 5 are allowed over the art of record.

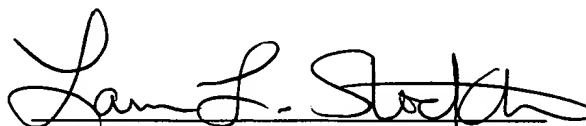
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have

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questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 19, 2005